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**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

AZUR PHARMA INC.,

Plaintiffs,

v.

TRIGEN LABORATORIES, INC.,

Defendant.

Civil Action No. 10 CV 207 (NRB)  
**Hon. Naomi Rice Buchwald**

**ANSWER, AFFIRMATIVE  
DEFENSES, AND  
COUNTERCLAIMS TO THE  
AMENDED COMPLAINT AND  
JURY DEMAND**

Defendant TRIGEN LABORATORIES, INC. ("TRIGEN"), for its Answer to the

Amended Complaint, responds as follows:

**NATURE OF THIS ACTION**

1. Admitted to the extent that Plaintiff Azur Pharma Inc.'s ("Azur") Complaint is brought under Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B), and otherwise denied.
2. Admitted.

3. Admitted to the extent that TRIGEN markets TRIGEN Products (Taron™ DHA and Folivane™) as lower cost alternatives to the Gesticare® Products, and otherwise denied.

4. Denied.

5. Denied.

6. Denied.

7. Denied.

8. Denied.

9. Denied.

10. TRIGEN lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 10, to the extent this paragraph requires a response, TRIGEN denies Azur has a right to relief.

#### **THE PARTIES**

11. Admitted.

12. Admitted.

#### **JURISDICTION AND VENUE**

13. Admitted to the extent that this Court has original jurisdiction under 15 U.S.C. § 1116 and 28 U.S.C. §§ 1331 and 1338, and otherwise denied.

14. Admitted.

15. Admitted.

#### **STATEMENT OF FACTS**

16. TRIGEN lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 16, and therefore denies the same.

17. TRIGEN lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 17, and therefore denies the same.

18. Admitted.

19. Admitted to the extent that calcium may inhibit iron absorption, and TRIGEN lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 19, and therefore denies the same.

20. TRIGEN lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 20, and therefore denies the same.

21. TRIGEN lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 21, and therefore denies the same.

22. TRIGEN lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 22, and therefore denies the same.

23. TRIGEN lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 23, and therefore denies the same.

24. TRIGEN lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 24, and therefore denies the same.

25. TRIGEN lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 25, and therefore denies the same.

26. Admitted to the extent TRIGEN has begun to market its lower cost alternatives TRIGEN Products (Taron™ DHA and Folivane™) to the Gesticare® Products, and denied otherwise.

27. TRIGEN objects to the inclusion of the undefined term "true bi-phasic release mechanism" in Paragraph 27. The inclusion of the undefined term renders the paragraph so

vague and ambiguous as not to be susceptible to an informed admission or denial. To the best of TRIGEN's understanding of the term, denied.

28. Denied.

29. Admitted to the extent that (i) Taron™ consists of a multivitamin/mineral tablet; (ii) Taron™ DHA consists of (a) a multi-vitamin/mineral tablet (which is the same as the Taron™ tablet) and (b) a red soft gel DHA capsule; and (iii) Folivane™ consists of (a) a multi-vitamin/mineral tablet and (b) a red soft gel DHA capsule (which is the same as the Taron™ DHA capsule).

30. Admitted to the extent that the red soft gel DHA capsule included with both the Taron™ DHA and Folivane™ products includes Eicosapentaenoic Acid ("EPA"), and otherwise denied.

31. Denied.

32. To the extent that the terminology "generic" in Paragraph 32 requires direct application or interpretation of the laws of the various states and the District of Columbia and/or regulations and policy of the United States Food and Drug Administration ("FDA"), TRIGEN objects and submits that no response is required, the terminology being so vague and ambiguous as not to be susceptible to an informed admission or denial. TRIGEN further objects to the terms "generic," "equivalent," and "alternative" being used interchangeably. On information and belief each term has a distinct definition. Subject to the foregoing, admitted to the extent that TRIGEN is well aware that pharmacists, and health care organizations, in the process of prescribing or approving payment for prescription drugs, consult drug data publishing services such as Medi-Span, First Databank, Red Book and Gold Standard. Also admitted to the extent that often, the

lower cost alternative will be the one dispensed, or the health care agency will insist on the less expensive alternative being dispensed and otherwise denied.

33. To the extent that the terminology "generic" in Paragraph 33 requires direct application or interpretation of the laws of the various states and the District of Columbia and/or regulations and policy of the FDA, TRIGEN objects and submits that no response is required, the terminology being so vague and ambiguous as not to be susceptible to an informed admission or denial. TRIGEN further objects to the terms "generic," "equivalent," and "alternative" being used interchangeably. On information and belief each term has a distinct definition. Subject to the foregoing, admitted to the extent at least one drug data publishing service has identified Taron™ DHA and Folivane™ as lower cost alternatives, which in turn may lead to numerous formularies and pharmacy systems listing Taron™ DHA and Folivane™ as substitutable products to Gesticare® Products, and denied otherwise.

34. Admitted.

35. To the extent that the terminology "generic" in Paragraph 35 requires direct application or interpretation of the laws of the various states and the District of Columbia and/or regulations and policy of the FDA, TRIGEN objects and submits that no response is required, the terminology being so vague and ambiguous as not to be susceptible to an informed admission or denial. TRIGEN further objects to the terms "generic" and "substitutes" being used interchangeably. On information and belief each term has a distinct definition. Subject to the foregoing, admitted to the extent that pharmacists and other participants in the marketplace for prescription drug products rely upon organization such as First Databank, Medi-Span, Red Book, and Gold Standard to identify potentially substitutable drugs, and otherwise denied.

36. Denied, including denied that patients' health and safety have been put at risk.

**FIRST CLAIM FOR RELIEF**  
**(Violation of the Lanham Act)**

37. TRIGEN refers to and incorporates herein its responses to the allegations of Paragraphs 1-36 above.

38. To the extent that the terminology "generic" in Paragraph 38 requires direct application or interpretation of the laws of the various states and the District of Columbia and/or regulations and policy of the FDA, TRIGEN objects and submits that no response is required, the terminology being so vague and ambiguous as not to be susceptible to an informed admission or denial. TRIGEN further objects to the terms "generic" and "equivalent" being used interchangeably. On information and belief each term has a distinct definition. Subject to the foregoing, admitted to the extent that TRIGEN markets, sells, and distributes the TRIGEN Products (Taron<sup>TM</sup> DHA and Folivane<sup>TM</sup>) as lower cost alternatives to the Gesticare<sup>®</sup> Products and otherwise denied.

39. To the extent that the terminology "generic" in Paragraph 39 requires direct application or interpretation of the laws of the various states and the District of Columbia and/or regulations and policy of the FDA, TRIGEN objects and submits that no response is required, the terminology being so vague and ambiguous as not to be susceptible to an informed admission or denial. TRIGEN further objects to the terms "generic," "identical," and "substitutes" being used interchangeably. On information and belief each term has a distinct definition. Subject to the foregoing, admitted to the extent that Azur has demanded that TRIGEN cease and desist from making any false or misleading claims that its products are generic, identical to, or a substitute for Azur's Gesticare<sup>®</sup> Products, or that induce drug data publishing services to list such products as identical to or a substitute for Azur's Gesticare<sup>®</sup> Products and otherwise denied.

40. Denied. TRIGEN has reviewed the concerns expressed by Azur and TRIGEN does not believe TRIGEN's actions are unlawful.

41. TRIGEN lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 41, and therefore denies the same.

**PLAINTIFF'S PRAYER FOR RELIEF**

TRIGEN denies that Azur is entitled to any of the requested relief.

WHEREFORE, TRIGEN respectfully requests that this Court enter judgment in its favor and against Azur on all of the claims set forth in the Compliant, and further that it award TRIGEN all of its costs and expenses incurred in connection with the defense of those claims, including its attorney's fees, this being an exceptional case under 15 U.S.C. § 117, along with any other relief the Court deems just and proper.

**AFFIRMATIVE DEFENSES**

42. TRIGEN sets forth the following defenses to AZUR's Complaint. TRIGEN's assertion of its affirmative defenses is not intended to alter the applicable burdens of proof on the parties, nor intended to limit its rights in any manner. TRIGEN expressly reserves the right to supplement the defenses below based upon any information of which it may become aware during the course of this action, and to assert any further defenses, positions, claims and counterclaims, of which TRIGEN becomes aware during discovery, or at trial, as applicable.

**FIRST AFFIRMATIVE DEFENSE**

43. The Complaint fails to state a claim on which relief can be granted.

**SECOND AFFIRMATIVE DEFENSE**

44. Azur's claims are barred because at all relevant times TRIGEN acted in good faith as a developer and promoter of the lawful TRIGEN Products.

**THIRD AFFIRMATIVE DEFENSE**

45. Azur's claims are barred because TRIGEN's representations, statements, and/or actions have at all times been truthful, accurate, and not false or misleading.

**FOURTH AFFIRMATIVE DEFENSE**

46. The claims for punitive damages are barred because TRIGEN did not act with malice or with reckless indifference to the rights of Azur and because TRIGEN always acted in good faith with respect to Azur.

**FIFTH AFFIRMATIVE DEFENSE**

47. There is no likelihood of confusion or mistake between Azur's Gesticare® Products and TRIGEN's Products that would cause Azur to lose goodwill of patients, physicians, pharmacists, and other participants in the marketplace for prescription drugs.

**SIXTH AFFIRMATIVE DEFENSE**

48. Azur has failed to allege, and TRIGEN is not aware of, any actual confusion between Azur's Gesticare® Products on the one hand and TRIGEN Products on the other.

**SEVENTH AFFIRMATIVE DEFENSE**

49. To the extent Azur has sustained any damages as a result of the claim asserted in the Complaint, such damages were self-inflicted, and were not the result of any act or omission on the part of TRIGEN.

**EIGHTH AFFIRMATIVE DEFENSE**

50. Azur's claims are barred, in whole or in part, by virtue of its failure to mitigate any damages it may have sustained.

**NINTH AFFIRMATIVE DEFENSE**

51. Azur's claims are barred because no actions or statements by TRIGEN has caused or contributed to any injuries or damages to Plaintiffs.

**TENTH AFFIRMATIVE DEFENSE**

52. Azur cannot demonstrate: a) any likelihood that the public will be confused, mislead, or deceived as to the source of products sold by TRIGEN, or b) that products sold by TRIGEN were not lawfully linked to Azur's Gesticare® products.

WHEREFORE, TRIGEN respectfully request that this Court enter judgment in its favor and against Azur on all of the claims set forth in the Complaint, that Azur's claims be dismissed with prejudice, and that TRIGEN be awarded attorneys' fees, costs, and expenses and such other and further relief as the Court deems just and proper.

**COUNTERCLAIMS**

**Parties, Jurisdiction and Venue**

53. Counter-Plaintiff TRIGEN Laboratories, Inc. ("TRIGEN") is a New Jersey corporation, having its principal place of business at 2400 Main Street, Suite 6, Sayreville, New Jersey 08872.

54. Counter-Defendant, Azur Pharma Inc. ("Azur") is a New York corporation, having its principal place of business at 1818 Market Street, Suite 2350, Philadelphia, Pennsylvania 19103.

55. These counterclaims arise under 15 U.S.C. § 1125(a)(1)(B).

56. This Court has original subject matter jurisdiction of these counterclaims under 15 U.S.C. § 1116, and under 28 U.S.C. §§ 1331 and 1338 for claims arising out of Azur's violations of Section 43(a) of the Lanham Act.

57. Venue of the counterclaims is proper in this district under 28 U.S.C. § 1391(a).

**STATEMENT OF FACTS**

58. TRIGEN is a private pharmaceutical company that produces low cost alternatives to brand drugs.

59. In and around January of 2010, TRIGEN began producing, marketing, and selling its Taron™ EC Calcium with DHA ("Taron™ DHA"), and Folivane™ EC Calcium DHA ("Folivane™") products.

60. TRIGEN has invested, and continues to invest, in the development, marketing, selling, and distribution of the Taron™ DHA and Folivane™ Products.

61. Upon information and belief, Azur began advertising, marketing, promoting, offering for sale, selling, and distributing its Gesticare®, Gesticare® with DHA, and Gesticare® with DHA DR (collectively, the "Gesticare® Products") in and around October of 2008.

62. Taron™ DHA is a low cost alternative for Gesticare® with DHA, and Folivane™ is a low cost alternative for Gesticare® with DHA DR.

63. Upon information and belief, Azur commercially advertises, markets, and promotes, the Gesticare® Products as including bi-phasic technology, meaning that the iron contained in the Gesticare® Products is immediately released upon entering the acidic stomach and the release of the calcium is delayed until the coated calcium granules enter the higher pH of the small intestine.

64. Upon information and belief, Azur commercially advertises and promotes the Gesticare® Products as including bi-phasic technology to influence doctors to prescribe, and consumers to buy, the Gesticare® Products.

65. Upon information and belief, Azur has invested, and continues to invest, in marketing, advertising and branding activities to publicize its Gesticare® Products as a bi-phasic

nutritional supplement for pregnant women and Azur has disseminated these advertisements and promotions to a large portion of the relevant purchasing public.

66. Upon information and belief, Azur's Gesticare® Products do not include bi-phasic technology in that the iron is not immediately released upon entering the acidic stomach and Azur's statements that the Gesticare® Products are bi-phasic are literally false or likely to deceive or confuse customers.

67. Azur's false statements regarding the Gesticare® Products are material and misrepresent the nature and characteristics of the Gesticare® Products.

68. Upon information and belief, both the Gesticare® with DHA and the Gesticare® with DHA DR products include amounts of Eicosapentaenoic Acid ("EPA"), yet neither the label for the Gesticare® with DHA product nor the label for the Gesticare® with DHA DR lists EPA as an ingredient of the Gesticare® with DHA or the Gesticare® with DHA DR products.

69. Upon information and belief, Azur does not properly test the presence of folic acid in the Gesticare® Products in accordance with United States Pharmacopeia ("USP") guidelines.

70. Upon information and belief, Azur has made, and continues to make, false and misleading representations of fact in its advertisements, promotional material, on its product packaging and product inserts regarding the ingredients, ingredient strengths, and the bi-phasic characteristics of the Gesticare® Products.

**COUNTERCLAIM 1**  
**(Violation of the Lanham Act)**

71. TRIGEN incorporates paragraphs 53 - 70 as if fully set forth herein.

72. Azur advertises, markets, promotes, sells, and distributes the Gesticare® Products as being bi-phasic, and as containing the ingredients at the strengths indicated on the labels and in the product inserts.

73. On information and belief, the Gesticare® Products are not bi-phasic, in that they do not immediately release iron at an initial time and then delay the release of calcium until a later time.

74. On information and belief, the Gesticare® Products do not contain the ingredients at the strengths indicated on the labels and in the product inserts.

75. Azur's acts of advertising, marketing, promoting, selling, and distributing the Gesticare® Products as bi-phasic and as containing the listed ingredients at the strengths indicated, constitute false and misleading descriptions of fact and false and misleading representations of fact in commercial advertising and promotion that misrepresent the nature, characteristics and qualities of the Gesticare® Products in violation of Section 43(a) of the Lanham Act.

76. Due to Azur's false advertising and misleading claims, TRIGEN will suffer actual damages in the form of lost sales and marketing opportunities, in an amount to be determined at trial, and will suffer both monetary damages and other damage and loss of market share, for which it has no adequate remedy at law.

WHEREFORE TRIGEN Laboratories, Inc. requests that this Court:

- (a) Enter judgment in favor of TRIGEN;
- (b) Grant a permanent injunction (1) enjoining Azur from falsely marketing, advertising, selling, or making claims that the Gesticare® Products are bi-phasic, that they contain the ingredients at the indicated strengths, or that they don't contain EPA;

- (c) Order Azur to pay compensatory damages to TRIGEN in an amount to be determined at trial;
- (d) Order Azur to pay treble damages pursuant to 15 U.S.C. § 1117;
- (e) Order Azur to disgorge all profits wrongfully derived from the false and misleading claims complained of herein pursuant to 15 U.S.C. § 1117;
- (f) Order Azur to pay TRIGEN's litigation expenses, including reasonable attorney's fees and costs of this action, pursuant to 15 U.S.C. § 1117'
- (g) Order Azur to pay prejudgment interests to TRIGEN; and
- (h) Award TRIGEN such other and further relief as the Court may deem just and proper.

**JURY DEMAND**

TRIGEN hereby demands a trial by jury on all issues so triable.

Respectfully submitted,

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Dated: March 30, 2010

*Attorneys for TRIGEN Laboratories, Inc.*

**CERTIFICATION**

I hereby certify that the matter in controversy is not the subject of any other court, arbitration or administrative proceeding.

Dated: New York, New York  
March 30, 2010

Andrew J. Bayne /s/  
Andrew J. Bayne (AB-1142)

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**CERTIFICATE OF SERVICE**

I hereby certify that on March 30, 2010 I served the foregoing **Answer, Affirmative Defenses and Counterclaims to Amended Complaint and Jury Demand** upon the following counsel via the ECF filing system in accordance with Local Civil Rule 5.2:

Stephen Wagner, Esq.  
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Dated: New York, New York  
March 30, 2010

Andrew J. Bayne /s/  
Andrew J. Bayne (AB-1142)

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